

K080244

pg 1 of 2

**510(k) Summary
Lux1540 Handpiece**

JUN 20 2008

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

1. SUBMITTER'S INFORMATION

NAME: Palomar Medical Technologies, Inc.

ADDRESS: 82 Cambridge Street
Burlington, MA 01803
Phone: (781) 993-2300
Fax: (781) 993-2330

CONTACT: Sharon Timberlake, RAC, CCRA
Director of Regulatory Affairs

DATE PREPARED: June 18, 2008

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Palomar Lux1540 Handpiece

COMMON/USUAL NAME: Lux1540

CLASSIFICATION NAME: Laser surgical instrument for use in general and
plastic surgery and in dermatology
(21 CFR § 878.4810)

PRODUCT CODE: GEX

3. PREDICATE DEVICES

Palomar Medical Technologies, Inc.
Lux1540 Handpiece
K060301 & K061652

Reliant Technologies, Inc.
Fraxel SR1500 Laser System (Fraxel Re:store™)
K070284, K062303, K042319

K080244

pg 2 of 2

4. INTENDED USE

The Palomar Lux1540 handpiece is intended for use in dermatological procedures requiring the coagulation of soft tissue, skin resurfacing procedures, melasma, acne scars, and surgical scars.

5. DEVICE DESCRIPTION

The Lux1540 Handpiece attaches to the StarLux Pulsed Light and Laser Systems. The complete system consists of a cart, system console, chiller, a footswitch, and a handpiece.

6. PERFORMANCE DATA

The specifications and indications for use of the Lux1540 handpiece are substantially equivalent to its predicate devices based on the data provided in the 510(k) premarket notification.

7. SUBSTANTIAL EQUIVALENCE

The Lux1540 Handpiece is substantially equivalent to its predicate devices when used according to its intended use. The information that is provided in this 510(k) premarket notification demonstrates that the Lux1540 Handpiece also shares the same technological characteristics, mechanism of action, intended use and physical properties to its predicates.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Palomar Medical Technologies, Inc.
% Ms. Sharon Timberlake, RAC, CCRA
Director of Regulatory Affairs
82 Cambridge Street
Burlington, MA 01803

JUN 20 2008

Re: K080244

Trade/Device Name: Palomar Lux1540 Handpiece
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic
surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 29, 2008
Received: May 30, 2008

Dear Ms. Timberlake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Sharon Timberlake, RAC, CCRA

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080244

Pg 1 of 1

Indications for Use

510(k) Number (if known): K080244

Device Name: Palomar Lux1540 Handpiece

Indications for Use:

The Palomar Lux1540 handpiece is intended for use in dermatological procedures requiring:

Coagulation of soft tissue, skin resurfacing procedures, melasma, acne scars, and surgical scars.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Boyd for xcm
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K080244